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10/081,641	02/22/2002	Patrick A. Haverkost	01-199US01 [209.0120001]	2371
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BROOKS, CAMERON & HUEBSCH, PLLC				LANG, AMY T
1221 NICOLLET AVENUE				
SUITE 500			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55403			3731	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/081,641	<b>Applicant(s)</b> HAVERKOST ET AL.
	<b>Examiner</b> AMY LANG	<b>Art Unit</b> 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 April 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1.3-29,31-33,47,48,50 and 51 is/are pending in the application.

4a) Of the above claim(s) 9,12-16,18-29,48 and 50 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1, 3-8, 10, 11, 17, 31-33, 47, and 51 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. In view of the appeal brief filed on 04/26/2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR **1.111** (if this Office action is non-final) or a reply under 37 CFR **1.113** (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR **41.31 followed by an appeal brief under 37 CFR 41.37**. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in **37 CFR 41.20** have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below (on the last page).

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 1, 3-8, 10, 11, 17, 31-33, and 47** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites wherein the anchoring means minimizes movement between the proximal end of the endoluminal device and body lumen (lines 18-20) so that it is directed to the embodiment wherein the anchoring means anchors the device against the lumen wall (see page 9, lines 8-31 of the instant specification). The claim also recites wherein the anchoring means is in the retrograde or anterograde portion (lines 14-15) and wherein the distal portion is unsheathed before the proximal end of the endoluminal device is anchored (16-17). However, the instant specification teaches that when the endoluminal device is within the retrograde portion, the retrograde sheath is retracted, the balloon inflated, and then the anterograde sheath is advanced to unsheathe a distal portion of the device (see page 9, lines 8-14 of the instant specification). Therefore, the specification only supports wherein the balloon is inflated before the distal end of the device unsheathed, when the anchoring means is within the retrograde portion. The specification does not support wherein the distal end of the endoluminal device is unsheathed before the proximal is anchored, as instantly claimed.

Similarly, claim 47 recites wherein the anchoring balloon is located under the retrograde sheath (lines 23-24) and then states wherein the distal portion of the endoluminal device is unsheathed before the proximal portion is anchored (lines 30-31).

Claims 3-8, 10, 11, 17, and 31-33 are dependent on claim 1 and therefore are not supported by the instant specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claim 6** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites wherein the retrograde sheath extends over the balloon anchoring means. However, claim 1, from which claim 6 depends, teaches that the anchoring means may be in either the retrograde or anterograde portion. Therefore, when the balloon anchoring means is located within the anterograde sheath (from claim 1), it is not clear as to how the balloon is also located under the retrograde sheath (from claim 6).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1, 10, 11, 32, 33, and 51** are rejected under 35 U.S.C. 102(b) as being anticipated by Euteneuer et al. (US 5,989,280).

With regard to **claim 1**, Euteneuer et al. (hereinafter Euteneuer) discloses an introducer for deployment of an endoluminal device in a body lumen (see entire document). As shown in Figure 1, the device comprises a shaft (50) and an inner

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sheath (12) mounted concentrically over the shaft. Stent (17) is then mounted concentrically over the shaft (Figure 1). Sleeve (16) is mounted over a distal portion of the stent so that distal movement of the sleeve unsheathes the distal portion of the stent (column 6, line 66 through column 7, line 10). Therefore sleeve (16) clearly overlaps the claimed anterograde sheath. Furthermore, this anterograde sheath of Euteneuer is indirectly attached to the proximal tip of the shaft (50).

Sleeve (14) therefore overlaps the claimed retrograde sheath since it is mounted over a proximal portion of the stent such that proximal movement of the sleeve unsheathes the proximal portion of the stent (column 6, line 66 through column 7, line 10). As shown in Figure 3, when the retrograde sheath is fully retracted the retrograde sheath and the anterograde sheath are laterally spaced from one another.

Euteneuer fully teaches bands (18 or 60) that anchor the stent to the inner sheath (column 7, line 22-50). The bands are constructed so that they dissolve in water when exposed within the patient. Therefore, when the anterograde sheath has been moved distally to expose the distal portion of the stent, then only the bands on this distal end are exposed and will dissolve. This causes only the distal portion of the stent to expand since the proximal portion is still secured under the retrograde sheath and by proximal bands that have not yet dissolved. Euteneuer teaches this embodiment where the distal end of the stent is released first (column 7, lines 41-46). Therefore, the anchoring means of Euteneuer are configured to engage and anchor only a proximal portion of the stent while the distal portion has been unsheathed. The bands also

minimize axial movement of the stent since it holds the stent in place against the inner sheath.

With regard to **claim 10**, L-seal (25) provides sufficient space between the inner sheath and the anterograde sheath to contain the stent and therefore overlaps the claimed radial spacer (column 6, lines 39-42).

With regard to **claim 11**, the radial spacer of Euteneuer is indirectly attached to the distal tip (Figure 2B).

With regard to **claim 32**, when only the anterograde sheath has moved proximally, the anterograde sheath and retrograde sheath are laterally spaced and the retrograde sheath has not moved.

With regard to **claims 33 and 51**, the anterograde sheath and retrograde sheath of Euteneuer laterally overlap and abut one another before either sheath has moved (Figure 1).

#### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Euteneuer et al. (US 5,989,280).

Euteneuer et al. (hereinafter Euteneuer) discloses the invention substantially as claimed wherein a stent is constrained by an anterograde and a retrograde sheath. However, Euteneuer does not specifically teach wherein the anterograde sheath extends a greater length over the stent than the retrograde portion. However, such would have been obvious at the time of the invention and involve a mere change in size. Additionally, the instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the device. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

11. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Euteneuer (US 5,989,280) in view of Zadno-Azizi et al. (US 6,022,336).

Euteneuer discloses the invention substantially as claimed wherein a stent is constrained by an anterograde and a retrograde sheath. However, Euteneuer does not disclose a medial sheath located between the inner sheath and the retrograde sheath.

Zadno-Azizi et al. (hereinafter Zadno-Azizi) teaches that a reinforcing layer, specifically a metal braid, is well known in the art to provide increased stiffness (column

9, lines 51-59). It is the examiner's position that such a reinforcing layer overlaps the instantly claimed sheath. It is further the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention for the introducer of Euteneuer to comprise an additional layer of a braided metal sheath between the inner sheath and retrograde sheath to provide increased stiffness.

Since Zadno-Azizi further teaches the advantage of providing variable stiffness along the length of an introducer (column 9, lines 51-54). Variable stiffness allows the introducer be sufficiently rigid to travel through a patient's vasculature but still flexible enough to allow for quick turns through torturous anatomy. The variable stiffness of Zadno-Azizi is accomplished by providing the proximal region with greater stiffness than the distal region. Therefore, it would have been obvious to one of ordinary skill in the art for the reinforcing braided sheath to terminate proximal the distal end portion of the introducer. This would produce a braided sheath that terminates proximal of the balloon.

12. **Claims 1, 3-6, 10, 11, 32, 47, and 51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn (US 5,201,757) in view of Helgerson et al. (US 5,695,499) and Sullivan et al. (US 6,607,551 B1).

With regard to **claims 1, 3, 6, and 47**, Heyn et al. (hereinafter Heyn) discloses an introducer to deploy an endoluminal device (see entire document). As shown in Figures 1 and 2, the introducer includes an anterograde portion comprising anterograde sheath (30), a retrograde portion comprising retrograde sheath (20 and 24), a shaft (44), and

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an inner sheath (100) (column 6, lines 47-50). Stent (18) is disposed concentrically over the inner sheath (100) and the shaft (78) (Figure 2; column 6, lines 47-54). The inner sheath is disposed over the shaft and the anterograde sheath is attached to the shaft distal tip through member (84) (Figure 2).

Heyn then teaches wherein the introducer is aligned at the target location (column 7, lines 17-21) and the anterograde sheath is moved relative to the inner sheath (column 6, lines 6-10). The retrograde sheath is also retracted proximally which allows the stent to expand and deploy (Figures 5a-5d). After the stent is fully expanded, the introducer is removed from the patient (column 8, lines 8-10).

However, Heyn does not specifically disclose an anchoring balloon.

Helgerson et al. (hereinafter Helgerson) teaches an anchoring sleeve (40) located on a catheter shaft (Figure 3). The sleeve acts as a stabilizer by holding the stent in place while the outer sheath is advanced to deploy the distal end of the device (column 5, lines 39-55; Figure 7). Furthermore, the sleeve advantageously provides such a strong hold on the stent that it anchors and stabilizes the stent to allow the sheath to then be retracted and recapture the stent to reposition the stent within the patient (column 5, lines 55-65).

However, Helgerson does not disclose the sleeve stabilizer as a balloon.

Sullivan et al. (hereinafter Sullivan) teaches inflatable protuberances that also act to stabilize the stent prior to deployment (column 8, lines 36-62). These inflatable protuberances engage the stent so that the stent is advantageously stabilized while the

sheath is retracted (column 5, lines 11-20). Additionally, the stabilizers are inflatable and therefore overlap the claimed balloon (column 8, line 46).

Since Helgerson teaches a stabilizer that advantageously holds the stent in place during deployment and allows for recapture and Sullivan teaches that it is well known in the art for stent stabilizers to be inflatable balloons, it would have been obvious at the time of the invention for the stent of Heyn to also be stabilized with an inflatable anchor. This would advantageously allow the Heyn stent to be anchored while the sheaths are unsheathed.

Since Helgerson teaches the stabilizer as located in only a proximal portion of the stent (column 5, lines 62-65), the device of Heyn in view of Helgerson and Sullivan would comprise a balloon anchoring means under the retrograde sheath. Therefore, the distal Heyn sheath is able to be advanced forward while the balloon anchor stabilizes the stent to the retrograde sheath. This would minimize axial movement of the stent since it holds the stent in place against the sheath.

With regard to **claim 4**, although Sullivan does not specifically disclose an inner lumen to inflate the anchoring balloon, Heyn teaches an inner lumen to inflate balloon (140), as is well known in the art. Since Heyn teaches the lumen to inflate one balloon, it would have been obvious at the time of the invention for the shaft to comprise a second lumen to inflate the anchoring balloon.

With regard to **claim 5**, as shown in Figure 3 of Helgerson, the anchoring balloon is mounted concentrically over the shaft.

With regard to **claims 10 and 11**, Heyn further teaches radial spacers (104) surrounding inner sheath (100) (column 6, lines 50-54). As shown in Figure 2, the spacers are attached to the distal tip (84) through the inner sheath.

With regard to **claim 32**, when the anterograde sheath is advanced before the retrograde sheath is retracted, the two sheaths are laterally spaced from each other before the retrograde sheath is retracted.

With regard to **claim 51**, as shown in Figure 1 of Heyn, the retrograde sheath and anterograde sheath initially abut one another since they are adjacent to each other.

13. **Claims 7, 8, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn (US 5,201,757) in view of Helgerson (US 5,695,499), Sullivan (US 6,607,551 B1), and Zadno-Azizi et al. (US 6,022,336).

Heyn in view of Helgerson and Sullivan discloses the invention substantially as claimed wherein a stent is constrained by an anterograde and a retrograde sheath. Heyn further teaches a shaft and inner sheath but does not disclose a medial sheath located between the inner sheath and the retrograde sheath.

Zadno-Azizi et al. (hereinafter Zadno-Azizi) teaches that a reinforcing layer, specifically a metal braid, is well known in the art to provide increased stiffness (column 9, lines 51-59). It is the examiner's position that such a reinforcing layer overlaps the instantly claimed sheath. It is further the examiner's position that it would have been obvious to one of ordinary skill in the art at the time of the invention for the introducer of

Heyn to comprise an additional layer of a braided metal sheath between the inner sheath and retrograde sheath to provide increased stiffness.

Since Zadno-Azizi further teaches the advantage of providing variable stiffness along the length of an introducer (column 9, lines 51-54). Variable stiffness allows the introducer be sufficiently rigid to travel through a patient's vasculature but still flexible enough to allow for quick turns through torturous anatomy. The variable stiffness of Zadno-Azizi is accomplished by providing the proximal region with greater stiffness than the distal region. Therefore, it would have been obvious to one of ordinary skill in the art for the reinforcing braided sheath to terminate proximal the distal end portion of the introducer. This would produce a braided sheath that terminates proximal of the balloon.

***Response to Arguments***

14. Applicant's arguments filed 04/26/2010 have been fully considered but they are not persuasive.

Specifically, applicant argues (A) that the guidewire of Euteneuer cannot overlap the claimed shaft.

With respect to argument (A), as shown in Figure 1 of Euteneuer, the guidewire (50) is shown as a long, generally cylindrical bar and therefore forms a shaft. Furthermore, the instant claims provide no structure regarding the claimed shaft. Therefore, it is the Examiner's position that a broad and reasonable interpretation allows a guidewire to overlap the claimed shaft.

Specifically, applicant argues (B) that sleeve (16) is not attached proximally to the distal tip of the shaft

With respect to argument (B), the shaft (50) of Euteneuer is attached to the proximal end of the device, at manifold (48). This proximal end of the device is attached to sleeve (16) through catheter (12). Therefore, the sleeve (16) is attached proximally to the distal tip.

Specifically, applicant argues (C) that sleeve (16) of Euteneuer does not have an open proximal end due to slipping seal (30).

With respect to argument (C), as shown in Figure 3, the proximal end of sleeve (16) is fitted around catheter (12) so that it forms an opening through which the catheter is inserted. This opening overlaps the claimed open proximal end.

Specifically, applicant argues (D) that the anchoring means of Euteneuer anchors the stent against the catheter and not against the lumen wall.

With respect to argument (D), the claims only recite wherein the relative axial movement between the stent and body lumen is minimized by the anchoring means. Therefore, although the anchoring means of Euteneuer anchors the stent to the catheter, since the catheter is held in place within the body lumen, the anchoring means also reduces this relative axial movement.

Specifically, applicant argues (E) that member (25) of Euteneuer is irrelevant to providing sufficient space between the catheter and sleeve (14 or 16).

With respect to argument (E), as shown in Figure 2b, member (25) is located between the inner sheath (12) and the anterograde sheath (16) so that it at least helps to provide space for the stent.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

07/26/2010  
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07/30/2010